

CUTANEOUS MANIFESTATIONS OF HIV INFECTION AND AIDS  
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National Institute of Arthritis and Musculoskeletal and Skin Diseases

The Skin Diseases Program supports research on the structure, function, and diseases of skin. This program announcement is to encourage submission of research grant applications in the area of cutaneous manifestations of human immunodeficiency virus (HIV) infection and diseases, including AIDS, that are caused by HIV infection. Research grant applications may be basic, clinical, or epidemiologic. Research mechanisms to support these studies include investigator-initiated research grants (R01), Clinical Investigator Awards (K08), First Independent Research and Transition (FIRST) Awards (R29), and Individual National Research Service Awards (F32).

The vast majority of patients with AIDS manifest cutaneous disease at some time during their illness. Patients with HIV infection not meeting the criteria for the diagnosis of AIDS also frequently manifest cutaneous disease. In addition, an exanthem that is associated with initial HIV infection in humans has been described; it precedes seroconversion to HIV positivity by weeks to months. The skin diseases seen in HIV infection encompass diseases for which the pathogenesis has yet to be elucidated, including psoriasis and seborrheic dermatitis; infectious diseases such as candidiasis and viral and bacterial infections; and malignancies, particularly Kaposi's sarcoma.

A previous program announcement (NIH Guide for Grants and Contracts, Vol. 17 No. 11, March 25, 1988) was published to stimulate research in this area.

This program announcement is designed to further encourage research grant applications to investigate basic, clinical, and epidemiologic aspects of these diverse cutaneous manifestations of HIV infection. Projects may be oriented specifically towards the cutaneous manifestations of HIV infection.

They may also be oriented towards utilizing the high incidence of skin disease in the HIV-infected and AIDS populations to investigate the pathogenesis of the idiopathic skin disease. Thus, we expect to obtain new information relevant to idiopathic skin diseases as well as a better understanding of the coexistence of AIDS and skin disease.

Among the broad spectrum of basic research projects encouraged are studies of disease pathophysiology and genetics. Clinical studies may include prevention of morbidity and mortality or amelioration of cutaneous complications.

Epidemiologic studies may focus on the etiology, risk factors for disease development and severity, natural history of disease, and prognosis for

developing disease. This includes descriptive studies of incidence, prevalence, morbidity, and mortality.

#### SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH and ADAMHA policy is that applicants for NIH/ADAMHA clinical research grants and cooperative agreements will be required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information should be included in the form PHS 398 in Section 2, A-D of the Research Plan AND summarized in Section 2, E, Human Subjects. Applicants/offerors are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans (including American Indians or Alaskan Natives), Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including but not limited to clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is

important to apply the results of the study broadly, and this should be addressed by applicants.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, the applicant must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

Investigators are encouraged to work with existing, or proposed, longitudinal data collection resources and cohorts of patients. Populations that may be included are those at increased risk for HIV infection, as well as HIV-positive cohorts who are clearly defined by their source of exposure. Investigators are encouraged to work with existing patient cohorts, such as the Multicenter AIDS Cohort Study (MACS), The HIV Pulmonary Complication Study, and the AIDS Clinical Trials Group.

## ELIGIBILITY

Nonprofit organizations and institutions, governments and their agencies, for-profit organizations, and individuals are eligible to apply.

## DEADLINE

Applications will be accepted in accordance with receipt dates for unsolicited AIDS R01 and R29 applications: January 2, May 1, and September 1 of each year. AIDS investigator-initiated applications received on these dates by the Division of Research Grants will be subjected to expedited review. Applicants for F32 awards must submit applications to meet the receipt dates listed in the instructions for those mechanisms.

## REVIEW PROCEDURES AND CRITERIA

All applications, except F32s, must be submitted on form PHS 398, rev. 10/88. Form PHS 416-1 must be used to submit F32 applications. Application kits are available at the business or grants and contracts office at most research and academic institutions. Additional application kits may be obtained from the Office of Grants Inquiries, Division of Research Grants, NIH, Westwood Building, Room 449, Bethesda, MD 20892, telephone (301) 496-7441. The phrase, "Cutaneous Manifestations of HIV Infection and AIDS, PA-91-63" must be typed at item 2 of the first page of the application form 398 or item 3 of the form 416-1. The original and 24 copies of an R01 or R29 application submitted for expedited review, or the original and 2 copies of a fellowship application must be sent to:

Application Receipt Office  
Division of Research Grants  
National Institutes of Health  
Westwood Building, Room 240  
Bethesda, MD 20892\*\*

Applications in response to this solicitation will be reviewed on a nationwide basis in competition with other research grant applications in accord with the expedited NIH peer review procedures for AIDS-related research. In order to expedite the review, PHS human subject certifications and animal welfare verifications must be submitted with the applications. Applications will first be reviewed for technical merit by initial review groups and then by the appropriate national advisory council. The review criteria customarily employed by the NIH for research grant applications will prevail.

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. In such a case, a letter of agreement from the Program Director of the GCRC must be included with the application material.

All PHS and NIH grant policies governing research project grants apply to applications received in response to this program announcement. Applications will be referred in accordance with normal procedures of the NIH Division of Research and Grants.

For further information contact:

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This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 78-410, as amended; 42 USC 241) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.